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John M. Guynn
WORKMAN NYDEGGER
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111

EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1619	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,571	JOHNSON, B. RON	
	Examiner	Art Unit	
	Donna Jagoe	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-50,52,53 and 55-73* is/are pending in the application.

4a) Of the above claim(s) *48-50 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-47,53 and 55-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/23/10 and 5/27/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and arguments filed September 13, 2010 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Claims 37-50, 52, 53 and 55-73 are pending in this application.

Claims 48-50 and 52 are withdrawn.

Claims 37-47, 53 and 55-73 have been examined on the merits.

Response to Arguments

Applicant's arguments filed September 10, 2010 have been fully considered but they are not persuasive. Applicant asserts that the Squires reference differs in that it teaches a "coating" on the surface of the treated area during the course of treatment. In response, the composition appears to be the same, benzalkonium chloride in an aqueous solvent such as alcohol, applied in the same manner (dabbing swabbing, sponging, brushing, or coating infected areas). The visible residue would be the same. Further, instant claim 37 does not state that there is NO residue on the surface of the disordered tissue. It states that there is no residue that is no significant residue. It is reasonable to expect that the composition of Squires would leave no 'significant' residue after it is fully penetrated as well.

Regarding Applicant's arguments drawn to the maintenance of a coating on the surface of the treated area during the course of treatment, Applicant's composition

similarly coats the surface although there is no "significant" residue that is visibly detectable. Applicant asserts that because there was a treatment failure noted in the Squires reference that it teaches away from the instant claims because more than one treatment was required. However, the instant specification notes that "when several treatments are used instead of a single, primary treatment, it is preferable to use a clean and sterile applicator for each repeated treatment" (specification, page 17). It is reasonable to assume that a malady, such as those associated with disordered tissues, such as a herpes virus infection would require a repeat treatment and as noted in the instant specification, there are indeed provisions for such a "repeated treatment". Further, it is reasonable to expect reapplication to be necessary of any formulation if it is washed off before it has completely absorbed.

Applicant further asserts that the combination of Squires and the Remington's Pharmaceutical Sciences reference neither teaches nor suggests this method of operation because Squires teaches that the composition forms a coating on the surface of the treated area while teaching nothing with respect to the ability of the composition to penetrate into and through the disordered tissue so as to form a reservoir of the composition in the manner recited in claim 38. In response to applicants arguments Squires teaches that the composition is applied by dabbing swabbing, sponging, brushing, or coating infected areas such as oral mucosa (instant claim 69), nasal mucosa, vaginal tissue (instant claim 68), labial tissue, anal tissue, peri-anal tissue, lips (instant claim 67), cutaneous tissue (instant claim 70), subcutaneous tissue ocular tissue, conjunctiva and eyelids (column 3, lines 29-49) and Remington's Pharmaceutical

Sciences, 1975, teaches that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph). It would have been made obvious to one of ordinary skill in art at the time it was made to rub or compress the disordered tissue when applying the composition motivated by the teaching of Squires that the composition is topically applied and the teaching of Remington's Pharmaceutical Sciences that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph).

Applicant notes that instant claim 53 recites that the formulation is applied so that it is no longer visible detectable on the disordered tissue within about two minutes after the application. In response, Squires teaches that all ingredients are water soluble in an aqueous solvent system. It is not expected that the medicament would be visible or leave a residue. Further, since the carrier, isopropyl alcohol, is a volatile substance, any remaining medicament that is not absorbed would be expected to volatize away, and not be visible after several minutes.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-47, 53 and 55-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

When considering new matter, the question is whether there is explicit, implicit or inherent disclosure.

MPEP § 2163 states that, "[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., In re Lukach, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); In re Smith, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads)." Further, the MPEP states, "[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." Instant claims 37 and 71-73 recite that the method of applying the treatment composition to disordered tissue "leaves no significant residue on a surface of the disordered tissue after penetrating into the disordered tissue". However, the instant specification recites "the content of the composition has different formulations; however, in the preferred embodiment there is no significant residue remaining after the composition has been applied and absorbed **that is visibly detectable** (see page 17 of the instant specification). This means that

the composition still forms a residue on the surface of the skin, albeit a clear residue (one that is not significant and one that is not visible detectable).

This is a new matter rejection.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-47, 53 and 55-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "significantly" in claims 37 and 71-73 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how "insignificant" a residue on the surface of disordered tissues can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "significant" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 37-47, 53 and 55-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Squires U.S. Patent No. 6,355,684 and Remington's Pharmaceutical Sciences, 1975.

Squires teaches treatment of herpes virus and other infections diseases (see title) such as herpes simplex (instant claim 63)(column 2, lines 25-30) comprising treatment with quaternary ammonium compounds having six to eight carbons (column 3, line 55 to column 4, line 9) such as benzalkonium chloride (see abstract, column 4, line 9, column 5, lines 35-45, column 6, lines 24-41, etc.) along with a solvent (see abstract) such as alcohol (column 4, line 27 and claim 14). The composition is applied

by dabbing swabbing, sponging, brushing, or coating infected areas such as oral mucosa (instant claim 69), nasal mucosa, vaginal tissue (instant claim 68), labial tissue, anal tissue, peri-anal tissue, lips (instant claim 67), cutaneous tissue (instant claim 70), subcutaneous tissue ocular tissue, conjunctiva and eyelids (column 3, lines 29-49). Treatment includes treatment of herpes and other related microbial infections including but not limited to herpes zoster (instant claim 64) (column 2, lines 25-31), The solution is applied in a bottle with an applicator (claims 43-45) (column 4, lines 19-22). It does not teach the size range of the contacting surface relative to the size of the disordered tissue, however, one having ordinary skill in the art could readily determine the size of an applicator required to treat a disorder arising from a virus, bacteria or fungus. Nothing unexpected is demonstrated by the size of the applicator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a towlette or a flat applicator to skin surface since the skin surface is flat thus achieving maximum contact with the skin. Regarding the formation of a reservoir upon application of the composition, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and In re Fitzgerald (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under

35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. In this case, Squires teach the same composition (benzalkonium chloride in an aqueous solvent such as alcohol) applied to the same malady (herpes or other infections of the cutaneous tissue or mucous membrane) in the same manner (dabbing swabbing, sponging, brushing, or coating infected areas). It is noted that Squires teaches a composition comprising Echinacea along with benzalkonium chloride, however, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts. Addressing the limitation of instant claims 37 drawn to "the treatment being effective in killing at least of viruses, bacteria or fungus after only a single application of the treatment composition to the disordered tissue", Squires teaches that topically in vivo the herpes simplex infections (a virus) was immediately arrested (column 9, lines 8-10) and when signs of an outbreak exhibited signaling the prodrome stage of an outbreak, the compound (medicine) was immediately applied by the subject and the outbreak was fully arrested and further symptoms never occurred (column 10, lines 40-46). Squires does not disclose the method wherein the carrier is 20-40% isopropyl alcohol or 70% isopropyl alcohol. Squires however, discloses a concentration of water in an amount of from 15-25% (column 6, lines 36-41) and isopropanol in a concentration of from 20-30% (column 18, lines 5-6) and 10-20% (column 18, lines 40-46). The recitation of the word "about" in instant claims 60-62 causes about 20% to about 40% (claim 60), about 60% to about 80% (claim 61) and about 70% (claim 62) isopropyl alcohol carrier to read on the prior art amount of 10-30% as noted supra. Traditionally, the term "about" permits some

tolerance. See, e.g., In re Ayers, 69 USPQ 109 (CCAP 1946), where "at least about 10%" was held to be anticipated by a teaching of a content "not to exceed about 8%." Note, however, that the courts have recently begun to interpret the term far more expansively. See, e.g., Conopco v. May, 24 USPQ2d 1721, 1736 (U.S. District Court, Eastern District of Missouri 1992), where four times was found within scope of "about", where the components of the respective compositions perform substantially the same function in substantially the same manner.

Squires does not disclose the method wherein the composition is no longer visible after about 2 minutes, or the composition leaves no significant residue on a surface of the disordered tissue, however, all ingredients are water soluble in an aqueous solvent system. It is not expected that the medicament would be visible or leave a residue. Further, since isopropyl alcohol is a volatile substance, any remaining medicament that is not absorbed would volatize away, and not be visible. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald(205* USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

Regarding the limitation of claims 39-42 wherein the method of treatment is by application of the composition by rubbing, rubbing back and forth or compressing the disordered tissue, Remington's Pharmaceutical Sciences, 1975, teaches that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph). It would have been made obvious to one of ordinary skill in art at the time it was made to rub or compress the disordered tissue when applying the composition motivated by the teaching of Squires that the composition is topically applied and the teaching of Remington's Pharmaceutical Sciences that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph). Addressing the limitations of instant claims 65 and 66, drawn to the method wherein the disordered tissue comprises at least one lesion caused by smallpox (virus) or anthrax bacteria, Squires teaches the composition to be effective for other microbial diseases encompassing viruses and bacteria (column 2, lines 46-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a composition of benzalkonium chloride in an aqueous solvent such as isopropanol and water to treat infections such as smallpox virus and anthrax bacteria motivated by the teaching of Squires that other microbial diseases such as bacteria and viruses can be treated with the composition as noted supra.

A reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht*

12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. § 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37-47, 53 and 55-73 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-73 of U.S. Patent No. 6,420,431. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, the conflicting claims differ in that while the treatment is applied to the disordered tissue and penetrates the skin in a rapid manner, it is without rapidly diffusing beyond the skin. Instant claim 37 requires that the treatment "rapidly diffuses beyond the disordered tissues", but does not state that it performs this "without rapidly diffusing beyond the skin". The active agents, such as benzalkonium chloride, carriers, such as alcohol and manner of applying the composition, rubbing or "vigorously agitating" are the same. As such, it would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in

this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Disclaiming each one of the conflicting double patenting references is necessary to avoid the problem of dual ownership of patents to patentably indistinct inventions in the event that the patent issuing from the application being examined ceases to be commonly owned with any one of the double patenting references that have issued or may issue as a patent. Note that 37 CFR 1.31(c)(3) requires that a terminal disclaimer include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the rejection. This requirement serves to avoid the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention (37 CFR 1.601(n)). See, e.g., In re Van Ornum, 686 F.2d 937, 944-48, 214 USPQ 761, 767*70 (CCPA 1982).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619

Donna Jagoe /D. J./
Examiner
Art Unit 1619

November 22, 2010